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10/540,305	12/19/2005	Franz Kerek	JCLA17225	6715

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EXAMINER	
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ART UNIT	PAPER NUMBER
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,305	KEREK, FRANZ	
	Examiner	Art Unit	
	SAMUEL W. LIU	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 33-47* is/are pending in the application.

4a) Of the above claim(s) *4-6,8,9,33-38 and 43-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7 and 39-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/7/06 & 12/19/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

Claims 1-9 and 33-47 are pending.

The amendment filed 3/24/08 which cancels claims 10-32 has been entered.

Election/Restrictions

Applicant's election (filed 3/24/08) of Group I, claims 1-3, 7 and 39-42 is acknowledged. Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 4-6, 8-9, 33-38 and 43-47 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Therefore, claims 1-3, 7 and 39-42 are examined in this Office action.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application "10260537.8" filed in Germany on 12/21/2002 which English version is "WO 2004/058813 A2" submitted by Applicants.

IDS

The references cited in the IDS filed 6/7/06 and the IDS filed 12/19/05 have been considered by Examiner.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. э 1.821(a)(1) and (a)(2). However, this application fails to fully comply with the requirements of 37 C.F.R. э 1.821

through 1.825; Applicants' attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990).

●At page 9, lines 20-24, 3 peptide sequences are disclosed without SEQ ID NO identifications.

●At page 11, lines 10, 20 and 32, 3 peptide sequences are disclosed without SEQ ID NO identifications.

● From page 19, line 7 to page 20, line 15, 11 peptide sequences are disclosed without SEQ ID NO identification.

●At page 23, lines 16-18, 3 peptide sequences are disclosed without SEQ ID NO identifications.

● In claims 1 and 3, the amino acid sequences of 3 (claims 1) and 11 (claim 3) polypeptides are disclosed without SEQ ID NO identifications.

If the noted sequences are in the sequence listing as filed, Applicants must amend the specification to identify the sequences appropriately by SEQ ID NO. If the noted sequences are not in the sequence listing as filed, Applicants must provide (1) a substitute copy of the sequence listing in both computer readable form (CRF) and paper copy, (2) an amendment directing its entry into the specification, (3) a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. э 1.821 (e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d), and (4) any amendment to the specification to identify the sequences appropriately by SEQ ID NO.

Objection to Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter.

(1) At Page 32, line 32, the trade-names "Herceptin®", "MabCampath®" and "MabThera®" should be capitalized wherever they appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

(2) At page 39, line30, the kinases "MAPKK", "MAPKK" and "MAPK" should be spelled out for the first instant use. See also, page 25, line 26, "NOESY" and "TOCSY".

(3) At page 49, line 23, "ATCC No. CCL-185" should be changed to "ATCC No. CCL-185™".

(4) The specification should make it clear for "the peptide BZT, CZT and DZT" at page 50, line 25, because the meaning of "BZT, CZT and DZT" is not apparent.

(5) The "Short description of the drawings" section lacks the description for Figure 4; and the brief description of Figure 2 should indicate the meaning of "ACN %" depicted in the figure thereof.

Claim Rejections - 35 USC § 101

35 U.S.C. §101 states:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 1-3 and 7 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claim 1 and dependent claims therefrom, as written, do not sufficiently distinguish over other polypeptide and proteins and as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products; e.g., naturally-occurring polypeptide "hellethionin A" as set forth in claim 3. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, *e.g.*, by insertion of "isolated" as disclosed at paragraph [0054] of instant Spec. See MPEP 2105.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 1-3, 7 and 39-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite becasue without sequence identifier, the three peptide "formulas" set forth in claim 1 cannot be identified. Claims 2-3, 7 and 39-42 are included in the rejection.

Claim 2 recites that "position 31 the amino acid D" and "position 33 the amino acid I However, a Cys is dictated to be at position 31 and 33 of the third formula of Claim 1. Therefore, the numbering set forth in Claim 2 is indefinite.

Claim 7 recites "salt derivatives", "cyclic derivatives" and "derivative with a modified backbone of the peptides". The Spec does not define these three phrases. The recitations are unclear (i) whether or not "salt derivatives" refers to the peptides covalently attached to or non-covalently associated with any mineral compound(s) or metal ions; (ii) whether or not "cyclic derivatives" refers to (A) the peptides wherein C-terminal carboxylic group, or/and N-terminal amine group or/and any side chains of said peptides are chemically cyclized, e.g., intramolecular disulfide(s), or (B) the peptide linked to any organic cyclic compound(s); and (iii) whether or not "derivative with a modified backbone of the peptides" refers to (A) an analog of peptide bond, e.g., thioamide derivative of "peptide bone" (see Abstract, pages 3092-3099 and Table 3, Sauve et al. (1985) *Can. J. Chem.*, 63, 3089-3101), or/and (B) an achiral peptide backbone containing peptides, or/and (C) any modification of nitrogen atom and/or oxygen atom of the peptide bond(s). The metes and bounds of the recitation are unclear.

*Examiner note: At paragraph [0080], the specification states that "'carbon suboxide derivative' is mentioned, this term comprises all of the chemical compounds described in DE 196 00 301. The preparation and characterization of the carbon suboxide derivatives is also described in DE 196 00 301 and EP 0 874 851 B1"; and thus, the specification provides description for "carbon suboxide derivative".

Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written description

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The factors considered in the Written Description requirement are (1) Actual reduction to practice; (2) Disclosure of drawings or structural chemical formulas; (3) Sufficient relevant identifying characteristics; (4) Method of making the claimed invention; (5) Level of skill and knowledge in the art; and (6) Predictability in the art. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP § 2163.

(1) Actual reduction to practice/(2) Disclosure of drawings or structural chemical formulas.

Claim 7 as written is directed to "cyclic derivative" (genus) and "derivative with modified backbone of the peptide" (genus) wherein the "peptide' refers to the peptide of claim 1. The Spec fails to describe chemical structure of representative species of said "genus" which encompasses enormous species or variants such as any inter- or intra-molecular cyclic derivatives, and any chemical modifications of any atoms/functional groups of the peptide backbones. Thus, no said derivatives are actually reduced to practice and thus the claim lacks actual reduction to practice. Therefore, applicants are not in possession of the "derivative" thereof.

(3) Sufficient relevant identifying characteristics

The current disclosure is directed to formulation of the claimed peptide in the pharmaceutical composition for treating disease caused by pathogens or autoimmune disease (see pages 8 and 29-30). Sufficient representative number of species for full scope of the "genus" is not disclosed. In the absence of description of this disclosure as well as correlation or structure and function of the derivatives thereof, one skilled in the art would nor known the inventors are entitled to patent the claimed product.

(4) Predictability in the art

The relative art (Evans et al. (1989) *Proc. Natl. Acad. Sci. USA*., 86, 5849-5853) teaches that iodination of *Pyrularia* thionin, a cysteine-rich polypeptide, which has overlapping structural feature of the instant claim 1 peptide, leads to loss of activity for hemolysis (see abstract). This suggests that chemical modification of the polypeptide/peptide at peptide backbone would result in inactive product. Without teaching correlation between the structure and function, level of unpredictability in the art is high.

(5) Level of skill and knowledge in the art:

The general knowledge and level of skill in the art do not supplement the omitted description with respect to species which are representative of the genus discussed above. In the absence of the representative species for the full scope of the genus claimed, adequate written description requires more than a mere statement that it is part of the invention. Without a correlation between structure and function (see above), the claims do little more than define the claimed invention by function. See *Eli Lilly*, 119, F.3d at 1568, 43USPQ2d at 1406. In this case, the specification and/or the art fails to teach a correlation between the “functional derivative”

(claim 7) and activity of treating a disease state (see withdrawn claims 33-38). Therefore, the specification does not satisfy the written description requirement.

Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Conclusion

No claims are allowed.

Discussion of the art

The prior art made of record and not currently relied upon in any rejections is considered pertinent to Applicants' disclosure:

[1] Andresen et al. (*Plant Mol. Biol.* (1992) 19, 193-204) teach a cysteine rich polypeptide "KSCCKNTTGRNCYNACRFAGGSRPVCATACGCKIISGPTCPRDYPK" (see page 200, Fig. 7B, the peptide sequences, residues 28 to74). This peptide has structural similarity to instant peptide formula of claim 1 "XXCCXXXXXXXCXXXCXXXXXXXXXCXXXCXC XXXXTXXCXXXXX" and which differs from the instant peptide in that amino acid residue 37 of the Andersen's peptide is "Gly" while the corresponding residue of instant peptide is "Thr". Thus, this reference is not considered to be the prior art.

[2] Krieger et al. (US Pat. No. 7309759 B2) teach thionin BTH6 polypeptide "KSCCKDTLARNCYNTCRFAGGSRPVCAGACRCKIISGPKCPSDYPK" (see Table 1, cols 13-14). This peptide has structural similarity to instant peptide formula of claim 1

"XXCCXXXXXXXCXXXCXXXXQXXXXCXXXCXCXXXXTXXCXXXXX" in that residue 23 of instant peptide is Gln (Q) whereas the corresponding residue of the Krieger et al. peptide is Arginine (R). Thus, this reference is not considered to be the prior

[3] Mackay et al. (*Eur. J. Biochem.* (1993) 218, 183-194) teach the polypeptide name "MT-20-I" which amino acid residues 20-68:
"GKCCRCGDACKCASGCGCSGCKVVCKCSGTCKCGCDCTGPTNCKCESGC" have similarity to the instant peptide formula:
"XXCCXXXXXXXCXXXCXXXXXXXXXXCXXXCXCXXXXXXXXCXXXXXX" with difference in that number of the underlined residues of "MT-20-I" are **9** whereas number of the corresponding underlined residues of instant peptide formula are **8**. Thus, this reference does not teach instant peptide, and therefore, is not considered to be the prior art.

[4] Hashimoto et al. (*J. Neurochem.* (20020 80, 426-437) teach that presenilin polypeptide induces neuronal cytotoxicity (see abstract), suggesting that the presenilin is a cytotoxic active molecule.

[5] Curtis et al. (US Pat. No. 7125687 B1) teach a "pen-1B" polypeptide of SEQ ID NO:25 (columns 61-66) which amino acid residues 30-67:
"**C**CTTCATTG**C**CTT**C**GGGCCTGCG**C**TCG**CC**CTTTA**T**GTC" reads on the instant peptide formula "**CC**XXXXXXX**C**XXX**C**XXXXXXXXX**C**XXX**C**X**C**XXXX**T**XXC" of residues 3-33 of the instant peptide set forth in claim 1 (see the "attachment"; wherein conservative Cys residues are in bold). Yet, in view of that the claim language of the peptides of instant claim 1 is closed, the Curtis et al. reference here is not considered to be the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragton, can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

/Samuel W Liu, Ph.D./
Examiner, Art Unit 1656
May 16, 2008

/Karen Cochrane Carlson, Ph.D./
Primary Examiner, Art Unit 1656